The Impact of Legislation on Future Technology Development

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In this paper I examine some of the factors influencing technology development and attempt to explain whether CLIA '88 enhances the opportunities or exacerbates the problems for U.S.-based technology development. The viewpoint I express is concentrated on the clinical chemistry segment of the diagnostics arena.

For several decades the U.S. has played a dominant role in the development and exploitation of technology in the field of diagnostic products. Today, this dominance is threatened by European and Asian companies that are producing cost- and clinically effective products. The rate at which this competition is growing is influenced by many factors, but it is of growing concern to many in the U.S. that recent federal legislation will further diminish American industry's capability to meet this foreign competition. The demanding standards of the federal government in general and of the Food and Drug Administration (FDA) in particular have served for many years to protect the patient from the sale and use of ineffective products. However, there are many indications that new regulations included in the Clinical Laboratory Improvement Amendments (CLIA) of 1988 will inhibit, or at least complicate, technology development through new and demanding requirements for performance and operating conditions.

The Need for New Legislation

Clinical chemistry in the U.S. entered the last decade of the 20th century with a most impressive record of technological development relative to other branches of pathology. Whatever criteria are used to measure progress, the achievements in instrumentation, reagents, and diagnostic kits have been considerable. This progress has been due, to a great extent, to realistic levels of bureaucracy (regulations on in-vitro diagnostics and good manufacturing practices enforced by the FDA) and a well-informed profession capable of selecting the appropriate product in a competitive marketplace. Existing regulations, FDA vigilance, and a responsible industry have ensured the withdrawal from the market of numerous ill-conceived products before any large-scale detriment to patient care. It is difficult to see how the new legislation of CLIA '88, with its demanding requirements for calibration and classifications of tests into categories that ignore technological achievement, will bring about measurable improvement in test performance.

Regulations primarily written to inhibit the performance of pap-smear testing by laboratories with questionable proficiency are being applied to an entire profession, clinical chemistry, that has had an impressive 30-year record of improving quality (1-6). Development and growth of proficiency testing programs of the College of American Pathologists (CAP) and the American Association for Clinical Chemistry indicate the diligence of the profession, and state-operated programs show no evidence of mass closings of laboratories or loss of licenses (personal communication, CAP).

Thus it is unlikely that new CLIA '88 legislation will bring much to the clinical chemistry laboratory other than increased costs, delay in new product introduction, and more bureaucracy for laboratory administration (7). It is ironic that CLIA '88 should be discussed during a period when the federal government has just enacted new legislation, the Safe Medical Devices Act of 1990, that provides much greater penalties on producers and users of all deficient medical products. This act, which became law on November 28, 1991, requires prompt notification of incidents (particularly if a death is involved). Failure to notify authorities can cause fines of $15,000 per violation. The object of the act is seen as another move by the FDA to eliminate bad medical devices.

The Process of Diagnostic Product Development

There are many stages in the development of a diagnostic product, and many factors influence priorities for the diagnostics manufacturer. For most manufacturers, there is a choice of three areas on which to concentrate expenditures: product reliability of existing products, product extension for existing products, and new product development. The first two areas carry little technological risk and have a high chance of revenue enhancement. The third is high risk technologically and cannot ensure a return of revenue.

Unfortunately, U.S. industry has emphasized the first two at the expense of the third, owing to the insistence on short-term gain. Moreover, the career risk encountered by marketing and research and development executives in the U.S. diagnostic industry when they concentrate on new-product development is such that the practice is often deemed unwise.

In this environment, where risk of job security for the non-U.S. executive is less and where the regulations abroad are less demanding, the development of new products is viewed more favorably by European and Asian corporations. The marked delay in the market introduction of the serum a-fetoprotein test in the U.S., nearly a decade after its introduction in Europe, illustrates the problem. Many experts are now concerned that the new (and effective) testing methods for human
immunodeficiency virus and hepatitis C may be used widely throughout the rest of the world well before American patients can benefit from the tests. It is essential that regulations such as CLIA '88 do not become a further hurdle to new-product development, thus threatening a well-established leadership position in diagnostic-product development.

Influence of Legislation on the Diagnostic Product

The existing requirements for new-product introduction, enforced by the FDA, are embodied in two major approval schemes, the 510(k) or Pre-Market Approval (PMA) regulations. The requirements ensure that the FDA can assess the performance and safety features of new products before giving approval for their release to the market. While the U.S. remains the largest marketplace for diagnostic products, these requirements will continue to play a key role in product development. However, 510(k) or PMA procedures play only a partial role in the long-term success of new products. In a free-market economy, cost of purchase and operation, ease and convenience of use and maintenance, and overall reliability are still key elements. Therefore, it is debatable, given a demanding clinical environment, what beneficial consequences derive from the FDA's involvement. Certainly, there is little evidence (8, 9) that European countries have less quality in clinical chemistry because of the absence of 510(k)- or PMA-like legislation.

The characteristics that point to success for certain established diagnostic products that enjoy long life cycles have little to do with FDA regulations, but more to do with features of the product that enhance and prolong market position. Product demise is rarely ascribable to regulation, but rather to the perception of quality, value, and performance as viewed by the user.

Users' Perception of CLIA '88 Benefits

Few experienced laboratorians have not used or encountered a diagnostic product that has been deficient in some area. In some cases, those products have been deficient in performance because of faulty manufacture of a component or reagent, rather than inappropriate design or specifications. In general, deficiencies are detected by quality-assurance programs, clinical feedback, and operator vigilance.

The benefits of CLIA '88, derived from increased requirements for calibration and for regulation and certification of tests permitted in a laboratory, will be difficult to measure. However, users will view the regulations in various ways:

• Operators will perceive an attempt to improve safety and reliability, while at the same time questioning cost effectiveness.
• Institutions will be concerned about situations that can jeopardize operation of an approved facility that can lose recognition for federal reimbursement.
• Patients will notice very little except increased costs.

Impact of Legislation on the Future

The most constant feature of the diagnostic industry during the past three decades has been change: change in technology, product style, and economics. It is imperative that federal legislation not inhibit this feature.

It is important that legislation change to keep pace with new-product development, allowing the rapid implementation of new, exciting, beneficial technology. As the role of new technological development increases, the need for flexibility becomes essential. It would be tragic if well-meaning legislation, aimed (e.g.) at the elimination of poorly performed pap tests, were to inhibit or delay the introduction of new products generally in the U.S. It would be of greater consequence if such practice further eroded U.S. dominance of this marketplace by permitting growth of development and marketplace elsewhere in the world. It is incumbent on the professional bodies within the U.S. medical profession to strive for flexible legislation that changes with, or anticipates, a rapidly changing industry and its technology.

References